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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,843	02/09/2001	Charles F. Milo	1849.16102B-CIP	8513

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EXAMINER

NGUYEN, VICTOR

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,843

Applicant(s)

MILO ET AL.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to a closure material to seal a puncture site, classified in class 606, subclass 214.
 - II. Claims 9-12, drawn to an introducer assembly to seal a puncture site, classified in class 604, subclass 164.01.
 - III. Claims 23-31, drawn to a method for introducing a closure material to seal a puncture site, classified in class 128, subclass 898.
 - IV. Claims 13-22, drawn to a formative component assembly which in use to seal a puncture site, classified in class 606, subclass 213.

Inventions II and IV are related as apparatus and process for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to dissect tissues away from blood vessel. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

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case, the combination as claimed does not require the particulars of the subcombination as claimed because the invention in group III can use a formative component assembly differently from the formative component assembly in group IV. The subcombination has separate utility such as formative component objects manually without the need of an applicator.

3. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Daniel. Ryan on September 17, 2002 a provisional election was made with traverse to prosecute the invention of group 1, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8 are rejected under 35 U.S.C. 102 (e) as being anticipated by Cruise et al (U.S. 6,371,975).

As to claim 1, Cruise et al shows in figures 2,4,10,11,22, col. 2, lines 4-17, an assembly (10) having a closure material including a mixture of first and second components (col. 2, lines 4-10); a catheter (20) having a distal end (28); wherein one nozzle (34) located adjacent the distal end (28); and wherein a structure (46) carried by the catheter (20) distal to one nozzle (34); wherein the structure (46) including an open configuration allowing blood flow through the structure (46).

As to claims 2-4, Cruise et al shows in figures 2,4,10,11,22, col. 2, lines 4-10, wherein the catheter (20) blocked the flow of fluid from the nozzle (34); wherein the solid closure material composition (col. 2, lines 4-10) formed a localized at the adjacent vessel puncture site; wherein a mechanism operated the structure (46) between a collapsed condition and an expanded condition (col. 6, lines 34-67 and col. 7, lines 4-12).

As to claims 5-8, Cruise et al shows in figures 2,4,10,11,22, wherein an introducer assembly (16) communicated with the catheter (20) lumen for dispensing the first and second components (col. 2, lines 4-10) into the catheter (20) lumen; wherein the introducer assembly

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(16) includes an air vent (col. 7, lines 4-12); and wherein the introducer assembly (16) includes a mixing chamber (22) to bring the first and second components (col. 2, lines 4-10) into a mixed condition before entering the catheter (20) lumen; wherein the introducer assembly (16) includes a closure composition test chamber (94).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,235,000 to Milo et al	U.S. Pat. No. 6,398,798 to Selmon et al
U.S. Pat. No. 5,279,565 to Klein	U.S. Pat. No. 5,269,755 to Bodicky
U.S. Pat. No. 5,611,775 to Machold	U.S. Pat. No. 5,087,244 to Wolinsky et al
U.S. Pat. No. 6,221,049 to Selmon	U.S. Pat. No. 6,217,549 to Selmon et al

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898.

The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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Victor X Nguyen
Examiner
Art Unit 3731

vn
September 22, 2002


KEVIN T. TRUONG
PRIMARY EXAMINER

9/29/02